

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 2381.0010000/MAC/DJN
INTERNATIONAL APPLICATION NO. PCT/AU2003/001209	INTERNATIONAL FILING DATE 16Sept2003 (16.09.2003)	U.S. APPLICATION NO. (If Known, see 37 CFR 1.5) 10/528,029
TITLE OF INVENTION Methods for Regulating Cancer		PRIORITY DATE CLAIMED 16 Sept 2002 (16.09.2002)
APPLICANT(S) FOR DO/EO/US Sally-Anne Stephenson		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> 1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). 		
Items 11 to 20 below concern document(s) or information included:		
<ol style="list-style-type: none"> 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/528,029		INTERNATIONAL APPLICATION NO. PCT/AU2003/001209		ATTORNEY'S DOCKET NUMBER 2381.0010000/MAC/DJN	
20. Other items or information: Two pages of Form PTO-1449 listing seven documents; Copies of the seven documents as listed on Form PTO-1449 (AL1, AR1-AT1 and AR2-AT2); and return postcard.					
The following fees have been submitted				CALCULATIONS PTO USE ONLY	
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300				\$	
22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))				\$	
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0				\$	
All other situations..... \$200					
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b))				\$	
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0				\$	
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100				\$	
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400					
All other situations..... \$500					
TOTAL OF 21, 22 and 23 =				0.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	- 20 =		x \$ 50	\$	
Independent claims	- 3 =		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
TOTAL OF ABOVE CALCULATIONS =				\$ 0.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
SUBTOTAL =				\$ 0.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
+ TOTAL NATIONAL FEE =				\$ 0.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
+ TOTAL FEES ENCLOSED =				\$ 0.00	
				Amount to be refunded:	\$
				Amount to be charged	\$

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0036. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

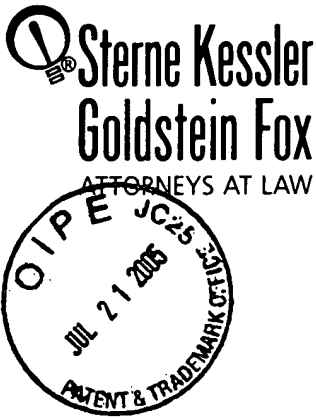
SEND ALL CORRESPONDENCE TO:

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Sterne, Kessler, Goldstein & Fox P.L.L.C.

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Michele A. Cimbala
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*Admitted only in Maryland
*Admitted only in Virginia
*Practice Limited to
Federal Agencies

July 21, 2005

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INTERNET ADDRESS:

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1645

Attn: Mail Stop Amendment

Re: U.S. Utility Patent Application
Application No. 10/528,029; § 371 Date: *(To be determined)*
(Nat'l Phase of Appl. No. PCT/AU2003/001209; I.A. Date: September 16, 2003)
For: **Methods for Regulating Cancer**
Inventor: Sally-Anne Stephenson
Our Ref: 2381.0010000/MAC/DJN *(formerly 2349.0000000/MAC/MGP)*

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning A Submission Under 35 U.S.C. 371;
2. Information Disclosure Statement Filing Under 37 C.F.R. § 1.97(b);
3. Two pages of Form PTO-1449 listing seven documents;
4. Copies of the seven documents as listed on Form PTO-1449 (AL1, AR1-AT1 and AR2-AT2); and
5. Return postcard.

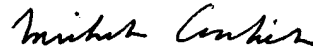
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
July 21, 2005
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Michele A. Cimbala
Attorney for Applicant
Registration No. 33,851

MAC/DJN:dbj
Enclosures

422780_1.DOC

REC'D

21 JUL 2005 #3

REC'D PCT/PTO

21 JUL 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Sally-Anne Stephenson

Appl. No.: 10/528,029 (U.S. Nat'l Phase
PCT/AU2003/001209; I.A. Filed: September
16, 2003)

For: **Methods for Regulating Cancer**

Confirmation No.: 9023

Art Unit: 1645

Examiner: *To be assigned*

Atty. Docket: 2381.0010000/MAC/DJN
(formerly 2349.0000000/MAC/MGP)

**Information Disclosure Statement
Filing Under 37 C.F.R. § 1.97(b)**

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents are submitted herewith.

The documents **AL1** and **AR1-AS2** were cited in a search report by a foreign patent office in the international application. The search report by the foreign office is also provided as document **AT2**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not at issue. Applicant has listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Michele A. Cimbala
Attorney for Applicant
Registration No. 33,851

Date: July 21, 2005

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Washington, D.C. 20005-3934
(202) 371-2600

415365_1.DOC

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
2381.0010000/MAC/DJN
(formerly 2349.0000000/MAC/MGP)

APPLICATION NO.
10/528,029 (Nat'l Phase of Appl. No.
PCT/AU2003/001209; I.A. filed:
September 16, 2003)

FIRST NAMED INVENTOR
Sally-Anne Stephenson

FILING DATE

ART UNIT
1645

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI3						
	AJ3						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 02/26827 A1	04/04/2002	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Bennett, B.D., <i>et al.</i> , "Cloning and Characterization of <i>HTK</i> , a Novel Transmembrane Tyrosine Kinase of the <i>EPH</i> Subfamily," <i>J. Biol. Chem.</i> 269:14211-14218, American Society for Biochemistry and Molecular Biology, Inc. (1994)
	AS	1	Hall, S.M., <i>et al.</i> , "Origin, Differentiation, and Maturation of Human Pulmonary Veins," <i>Am. J. Respir. Cell. Mol. Biol.</i> 26:333-340, American Thoracic Society (March, 2002)
	AT	1	Liu, W., <i>et al.</i> , "Coexpression of Ephrin-Bs and their Receptors in Colon Carcinoma," <i>Cancer</i> 94:934-939, John Wiley & Sons, Inc. (February, 2002)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
2381.0010000/MAC/DJN
(formerly 2349.0000000/MAC/MGP)

APPLICATION NO.
10/528,029 (Nat'l Phase of Appl. No.
PCT/AU2003/001209; i.A. filed:
September 16, 2003)

FIRST NAMED INVENTOR
Sally-Anne Stephenson

FILING DATE

ART UNIT
1645

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Stephenson, S.-A., <i>et al.</i> , "Receptor protein tyrosine kinase EphB4 is up-regulated in colon cancer," <i>BMC Mol. Biol.</i> 2:15, BioMed Central (December, 2001)
	AS	<u>2</u>	Takai, N., <i>et al.</i> , "Expression of receptor tyrosine kinase EphB4 and its ligand ephrin-B2 is associated with malignant potential in endometrial cancer," <i>Oncol. Reports</i> 8:567-573, University of Crete, Faculty of Medicine, Laboratory of Clinical Virology (May, 2001)
	AT	<u>2</u>	International Search Report for International Application No. PCT/AU03/01209, Australian Patent Office, Australia, mailed on October 23, 2003

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.